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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,083	05/23/2001	Mitchell S. Wortzman	01-40076-US	1801

7590

10/02/2002

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EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/02/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,083

Applicant(s)

WORTZMAN ET AL.

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-116 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-116 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-23, drawn to a composition comprising hydroquinone and a cationic salt of ascorbyl esters.
 - II. Claims 24-53, drawn to a composition comprising hydroquinone; a cationic salt of ascorbyl esters; and a protected retinoid, optionally with metabisulfite.
 - III. Claims 54-76, drawn to a method of stabilizing a hydroquinone composition by adding a cationic salt of ascorbyl esters .
 - IV. Claims 77-105, drawn to a method of stabilizing a hydroquinone composition by adding a cationic salt of ascorbyl esters and an protected retinoid.
 - V. Claim 106, drawn to a process of making a hydroquinone composition comprising steps as claimed.
 - VI. Claims 77-105, drawn to a method of stabilizing a mixture of hydroquinone composition and one or more protected retinoids by maintaining pH of the composition at about 5.5 to about 8.0.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-II ; and IV-VI are related as product and process of stabilizing or making a product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially

different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). For instance, hydroquinone composition can be stabilized by citric acid as evidenced by US3855150.

3. The invention I and II are directed to a combinational composition. Each invention is directed to a composition accompanying with materially different ingredients, and the beneficial effect that is patentably distinct subject matter. Thus, each invention is patentably distinct under 35 U.S.C. 103(a). Should applicant traverse on the ground that these combination compositions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Inventions III, IV and VI are directed to a method of stabilizing the hydroquinone containing combination compounds. However each combination composition used in each invention is patentably distinct composition as mentioned immediately above and since the product is not allowable, restriction is proper between said method of making and method of stabilizing.

5. Inventions III, IV(or VI) and V are related as process of stabilizing and making the product. The use as claimed cannot be practiced with a materially different materials and manufacturing techniques involved as evidenced by US5571841. Since the

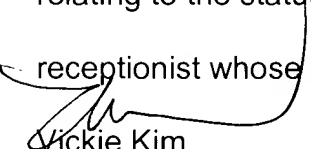
Art Unit: 1614

product is not allowable, restriction is proper between said method of making and method of stabilizing.

6. Because these inventions I-VI are distinct for the reasons given above and have acquired a separate status in the art and the search required for each group is not same, wherein a reference which anticipates the invention of Group I would not render the invention of Group II-V or VI obvious, absent ancillary art, restriction for examination purposes as indicated is proper. Even if there were unity of classification, the search of entire groups and/or genus in the non-patent literature(especially, non-patent literature) and database search (a significant part of a thorough examination) would be burdensome, it is undue burden for examiner for the accurate and proper examination, restriction for examination purposes as indicated is proper.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the

receptionist whose telephone number is 703-308-1235.


Vickie Kim,
Patent examiner
October 1, 2002
Art unit 1614